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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,373	12/27/2001	Hideji Tajima	10287.48	5376
27683	7590	06/15/2005		
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			EXAMINER	DO, PENSEE T
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/042,373	TAJIMA ET AL.
Examiner	Art Unit	
Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 April 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 22-26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-26, 28-33 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Amendment Entry & Claim Status***

The amendment filed on April 3, 2005 has been acknowledged and entered.\

Claims 22-26, 28-33 are pending.

Per Applicants' request, it is now corrected that the correct filing date of the previous response is May 21, 2004 instead of August 3, 2004. Applicants can check the correct filing date on PAIR system, see <http://pair-direct.uspto.gov>.

### ***Maintained Rejection(s)***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-26, 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, line 4, "capable of" is indefinite because it is unclear of what is being modified for the carriers to be capable of holding micro-substances and the remote-acting bodies. See also claims 24 and 25 for the same problem. See also claim 27 for "capable of" holding the micro-substances and the remote-acting bodies.

Claim 22, lines 8-9 are unclear as to how the remote-acting bodies and micro substances are held to the carrier by agitation. Agitation should remove anything attached to the carrier since there is no means recited on the carrier that can hold the remote-acting bodies and the micro substances.

Claim 24, lines 7-8 are not clear of how the carrier does the "holding" with agitation. (see explanation in rejection of claim 22).

Claim 25, in lines 8-9, it is unclear of how the carrier does the holding with agitation.(see explanation in rejection of claim 22).

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23, 25-28, 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest et al. (US 4,659,678).

Forrest et al. teach a method of immunoassay of an antigen in a liquid sample comprising mixing the antigen (micro-substance), magnetic cellulose particles (remote-acting bodies and carriers) bound to antibodies to the antigen known as the antibody reagent; the mixture is incubated for a certain amount of time; a magnetic field (remote force) is applied to separate the bound from unbound. The antibody reagent comprises of anti-FITC polyclonal antibody covalently coupled with magnetizable cellulose particles which are composites of cellulose containing black ferric(ous) oxide (Fe<sub>3</sub>O<sub>4</sub>). Magnetic field can be used to manipulate or separate the antigen-bound antibody-magnetizable cellulose particles from the unbound antibody-magnetizable particles.

Art Unit: 1641

(See col. 3, lines 30-56; col. 8, lines 15-40). The magnetic particles of Forrest are equivalent to the carrier and the remote-acting bodies of the claimed invention. Since the claimed invention fails to exclude that the carriers and the remote-acting bodies are separate entities, the magnetic cellulose particles which are composite of cellulose containing black ferric(ous) oxide ( $Fe_3O_4$ ) read on the claimed carrier and remote-acting bodies. The target analytes can be proteins, immunoglobulins, which include antibodies. Antibiotics include antibodies. (see abstract). Prior to pouring, the carriers, the remote-acting bodies and the micro-substances are separately prepared. To start out the preparation of the magnetizable cellulose particle, the cellulose and the magnetic particles have to be prepared separately before they are mixed. Since Forrest teaches mixing the suspension after incubation, agitation must have taken place. The specification of the present invention describes that the carriers that have a plurality of holes, cavities, concavities, or convexities are made up of cellulose and Forrest teaches that magnetic particles comprises cellulose and magnetite, the cellulose in Forrest must have a plurality of holes, cavities, concavities or convexities because these carriers are made up of the same material. In Forrest, since the magnetite or remote-acting bodies are fixed to the holes, cavities, etc. of the cellulose, and the antigen/micro-substance is fixed to the magnetic particles, the antigen/micro-substance must be fixed to the holes, cavities etc. of the carrier or cellulose as well. Thus, the requirements of claims 27 and 28 are satisfied. Regarding new claim 32, wherein the agitating includes using a mechanical force, there must be some kind of mechanical force occurring during mixing since Forrest teaches mixing the suspension. Regarding claim 33, since Forrest

teaches that applying a magnetic field to the magnetic cellulose particles to separate or concentrate the bound from the unbound, the magnetic particles must undergo orientation in response to the magnetic field. Therefore, it is inherent that the holes, cavities of the magnetic cellulose particles are large enough.

***New Ground(s) of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-26, 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to teach that the remote-acting bodies and the micro-substances be *independently* held in the holes, cavities, concavities or convexities in the surfaces of the carriers.

***Response to Arguments***

Applicant's arguments filed April 3, 2005 have been fully considered but they are not persuasive.

Regarding the 112, 2<sup>nd</sup> paragraph rejections, Applicants fail to correct all the rejections. Therefore, some of the 112, 2<sup>nd</sup> paragraph rejections are still maintained.

Regarding the 102 rejection for claims 22 and 25, Applicants submit that Forrest teaches that micro substances are coupled to magnetic particles and this is through covalent binding. In contrast, claims 22 and 25 recite making the remote-acting bodies and the micro substances be independently held in the holes, cavities, etc. in the surface of the carriers. Micro-substances are held to the carrier and in a manner other than covalent. In addition, Forrest explains that the magnetizable cellulose particles were a composite of cellulose containing approximately 50% black ferric(ous) oxide ( $\text{Fe}_3\text{O}_4$ ). In other words, the carriers of Forrest already contain the magnetic bodies before they are ever exposed to any micro-substances. In contrast, claims 22 and 25 recite making the remote-acting bodies and the micro-substances be independently held in the holes, cavities, etc. by simultaneously agitating the remote-acting bodies. The single agitating step is used to cause both the remote-acting bodies and the micro-substances to be held to the carriers, which is a more efficient and cost-effective approach than that in Forrest.

In Forrest method, the antigen (micro-substance), magnetic cellulose particles (remote-acting bodies and carriers) bound to antibodies are added one by one to a container to form a mixture. As the mixture is incubated and agitated, the complex between the magnetizable cellulose particle (remote-acting bodies and carriers) bound with an antibody and the antigen is formed. The antigen, which is the micro-substance, is carried on the cellulose, which in turns carry the magnetic particles. Thus, the magnetic particles and the antigen are being held independently from each other. The magnetic particles are not bound to the antigen, but rather the antibody on the magnetic

particles binds to the antigen. Regarding the make-up of the magnetizable cellulose particles, Applicants' argument is not on point because as explained above, after the agitation step, the remote-acting bodies and the micro-substances are independently held in the holes, cavities of the surface of the carriers. Once again, the remote-acting bodies (magnetic particles within the cellulose) are not directly bound to the micro-substance. Rather, the antibody bound to the surface of the cellulose particles binds to the antigen (micro-substance). Therefore, the antigens and the magnetic particles are being held by the cellulose particles independently after the agitating step.

***Allowable Subject Matter***

Claims 24, 29, and 30 are free of prior arts.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
June 9, 2005

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

06/13/05